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Signed: _____ Dated: 08/23/2007

Anna Tran

PATENT

In the United States Patent and Trademark Office

Applicant: Schuler et al.
Applicant's Ref: 0064.00
Application No: 09/852,408
Filed: May 9, 2001
Title: LOCKOUT MECHANISM FOR AEROSOL DRUG DELIVERY DEVICES

Examiner: Nihir B. Patel
Group Art Unit: 3772
Confirmation No: 5388

APPEAL BRIEF

Mails Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Examiner's Final Rejection of July 26, 2006, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

(1) ***Real Party in Interest***

The real party in interest of the present application is Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.), having a place of business at 150 Industrial Road; San Carlos, California 94707.

(2) ***Related Appeals and Interferences***

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) ***Status of Claims***

Claims 1-36 are presently pending in the case. Claims 1-36 8 and 10-17 have been finally rejected. The rejection of each of claims 1-36 is hereby appealed.

(4) ***Status of Amendments***

No amendments after Final Rejection have been filed. Accordingly, all amendments made during prosecution of the case have been entered.

(5) ***Summary of the Claimed Subject Matter***

As described in the specification at pages 9-15, as shown in the drawings in Figures 1-3, and as set forth in independent claims 1 and 17, an aerosol drug delivery system comprises a disposable container 52 adapted to contain a drug formulation. An aerosol generator aerosolizes the drug formulation in response to manual actuation, and an electronic prevention device 42 prevents manual actuation thereby preventing aerosolization of the drug formulation when in an inactive state and which permits manual actuation thereby permitting aerosolization of the drug formulation when an electric current is supplied to place the prevention device in an activated state. Other embodiments are shown in Figures 4-17.

As set forth in claim 28, an aerosol drug delivery system comprises a housing 44 having a mouthpiece 46. A canister 52 is movable within the housing when manually depressed into the housing, the canister having a metering valve 56 that is operable to release a metered amount of a drug formulation from the canister. A control system comprises a locking

mechanism that may be in an activate or an inactivate state, wherein the control system controls the opening of the valve such that the valve is only opened when a force is manually applied to depress the canister into the housing and when a dosing condition has been satisfied at which time the locking mechanism in the active state.

As set forth in claim 32 and as described at pages 20 and 21 of the specification, a method for administering a nicotine formulation for smoking cessation therapy comprises providing an amount of a nicotine formulation, preventing the aerosolization of the nicotine formulation with a lockout device when the lockout device is in an inactive state, supplying electric current to the lockout device to place the lockout device in an active state, and aerosolizing the nicotine formulation by manual actuation.

(6) ***Grounds of Rejection to be Reviewed on Appeal***

Appellant requests review of the Examiner's following grounds of rejection:

Claims 1-9, 11-18, and 24-27 have been rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,692,492 to Bruna et al (hereinafter Bruna et al).

Claims 34-36 have been rejected under 35 USC 103(a) as being unpatentable over Bruna et al in view of U.S. Patent 6,024,097 to Von Wielligh (hereinafter Von Wielligh).

Claims 19-22 have been rejected under 35 USC 103(a) as being unpatentable over Bruna et al in view of U.S. Patent 5,694,919 to Rubsamen et al (hereinafter Rubsamen et al).

(7) ***Argument***

Appellant believes each of claims 1-36 are improperly rejected and are therefore allowable for the following reasons.

The rejection under 35 U.S.C. 102(b) is improper

The Examiner's rejection of claims 1-9, 11-18, and 24-27 under 35 USC 102(b) as being anticipated by Bruna et al is improper. The rejection is traversed.

Bruna et al et al does not anticipate claim 1, for example. Claim 1 is to an aerosol drug delivery system comprising, inter alia, a disposable container adapted to contain a drug formulation and an aerosol generator for aerosolizing the drug formulation in response to manual actuation. In contrast, Bruna et al describes an automatic, electronically controlled system of actuation. As discussed in column 8 line 66 through column 9 line 13 and onward, the Bruna et al system detects the patient's inspiratory pressure and automatically actuates the device in response thereto. Thus, in contrast to present claim 1, Bruna et al does not disclose an aerosol generator for aerosolizing the drug formulation in response to ***manual actuation***.

The Examiner's position that Bruna et al does teach manual actuation is without merit or basis. The Examiner considers suction applied by the patient to be "manual actuation." This contention is incorrect and improper. According to the Merriam-Webster on-line dictionary, the following can be located for the term "manual":

Etymology:

Middle English *manuel*, from Anglo-French, from Latin *manualis*, from *manus* hand; akin to Old English *mund* hand and perhaps to Greek *marē* hand

Date: 15th century

1 a: of, relating to, or involving the hands <*manual* dexterity> b: worked or done by hand and not by machine <a *manual* transmission> <*manual* computation> <*manual* indexing>

2: requiring or using physical skill and energy <*manual* labor> <*manual* workers>

Nothing within this definition would suggest to one of ordinary skill in the art that suction would be encompassed by the expression "manual". Furthermore, Appellant's specification sets forth what is meant by the term "manual." For example, page 5 of the application provides a discussion of how the device is operated. Lines 23 and 24 recite "when a force is manually applied to depress the canister into the housing..." Since the standard dictionary definition and the Appellant's specification are in accord, it is improper for the Examiner to stretch the meaning of the term "manually" beyond normal bounds.

Since Bruna et al does not disclose all positively recited features, a section 102 rejection is precluded. Thus, the Examiner is respectfully requested to reconsider the language of claim 1 and withdraw the rejection thereunder.

Claim 17 is also not anticipated by Bruna et al. Claim 17 is to a method of aerosolizing a drug formulation comprising, inter alia, providing a container having an amount of a drug formulation that is aerosolized in response to ***manual actuation***. Bruna et al does not disclose a container containing a drug formulation that is aerosolized in response to manual actuation, as discussed above. Thus, Bruna et al does not anticipate claim 17.

Furthermore, claim 28 is not anticipated by Bruna et al. Claim 28 is to an aerosol drug delivery system comprising, inter alia, a control system that controls the opening of a valve such that the valve is only opened ***when a force is manually applied*** to depress the canister into the housing and when a dosing condition has been satisfied at which time a locking mechanism is in an active state. Bruna et al does not disclose this feature and does not anticipate the claim.

Claims 2-16 depend from claim 1; claims 18-27 depend from claim 17; and claims 29-33 depend from claim 28. Each of these dependent claims are not anticipated by Bruna et al for at least the same reasons as the claim from which they depend.

The rejections under 35 U.S.C. 103(a) are also improper

The Examiner rejected claims 34-36 under 35 USC 103(a) as being unpatentable over Bruna et al in view of U.S. Patent 6,024,097 to Von Wielligh (hereinafter Von Wielligh). The rejection is traversed.

Bruna et al and Von Wielligh do not render claim 34 unpatentable. Claim 34 is to a method for administering a nicotine formulation comprising, inter alia, preventing the aerosolization of the nicotine formulation with a lockout device when the lockout device is in an inactive state, supplying electric current to the lockout device to place the lockout device in an active state, and aerosolizing the nicotine formulation by manual actuation. Bruna et al does not disclose a lockout device for a manually actuated aerosolization device, as discussed above. Von Wielligh is relied on to teach a nicotine formulation and in that regard does not make up for the deficiencies of Bruna et al. In addition, the electronic device and the teachings of Bruna et al would be rendered inoperative if modified in a manner which resulted in Appellant's claim 34. Claims 35 and 36 depend from claim 34 and are also not rendered unpatentable by Bruna et al and Von Wielligh.

The Examiner rejected claims 19-22 under 35 USC 103(a) as being unpatentable over Bruna et al in view of U.S. Patent 5,694,919 to Rubsamen et al (hereinafter Rubsamen et al). The rejection is traversed.

Claims 19-22 depend from claim 17 which is not rendered unpatentable by Bruna et al, as discussed above. Rubsamen et al does not disclose the features that Bruna et al is lacking. Accordingly, the combination of references does not render claims 19-22 unpatentable.

The Examiner rejected claims 28-32 under 35 USC 103(a) as being unpatentable over Bruna et al in view of U.S. Patent 5,724,986 to Jones, Jr. et al (hereinafter Jones, Jr. et al). The rejection is traversed.

Bruna et al and Jones, Jr. et al do not render claims 28-32 unpatentable. Independent claim 28 is to an aerosol drug delivery system comprising, inter alia, a control system that controls the opening of a valve such that the valve is only opened when a force is manually applied to depress a canister into a housing. Bruna et al does not disclose this feature, as discussed above. In addition, it would not have been obvious to one of ordinary skill in the art to modify Bruna et al in view of the teachings of Jones, Jr. et al to arrive at Appellant's invention. If one were to make the Bruna et al valve only open when a force is manually applied would render the device of Bruna et al and the teachings of the reference inoperative. Accordingly, the modification proposed by the Examiner would not be obvious, and claim 28 and the claims depending therefrom are not render unpatentable by the references.

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Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

NEKTAR THERAPEUTICS
(formerly INHALE THERAPEUTIC SYSTEMS)

Dated: 23 AUG 2007

By: _____
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(8) Claims Appendix

1. An aerosol drug delivery system comprising:

a disposable container adapted to contain a drug formulation;

an aerosol generator for aerosolizing the drug formulation in response to manual actuation; and

an electronic prevention device which prevents manual actuation thereby preventing aerosolization of the drug formulation when in an inactive state and which permits manual actuation thereby permitting aerosolization of the drug formulation when an electric current is supplied to place the prevention device in an activated state.

2. A system as in claim 1, wherein the prevention device comprises an electronic lockout device having a lockout element that is positioned in a dose preventing position when in the inactive state, and is movable to a dosing permitting position when electric current is supplied to place the lockout device in the activated state.

3. A system as in claim 2, wherein the lockout device further comprises circuitry for supplying electrical current to move the lockout element to the dose permitting position when the lockout device is in the activated state.

4. A system as in claim 2, wherein the lockout device further comprises a controller having an associated memory for storing a dosing condition, and wherein the controller is configured to send a signal to place the lockout device in the activated state only after the dosing condition has been satisfied.

5. A system as in claim 2, wherein the container comprises a canister, and wherein the aerosol generator comprises a metering valve and an actuator operably coupled to the canister.

6. A system as in claim 5, further comprising a housing, wherein the canister is reciprocally held within at least a portion of the housing between a home position and a dosing position where the actuator is engaged to open the metering valve and to permit the escape of a metered amount of the drug formulation from the canister.

7. A system as in claim 6, wherein the lockout element is positioned to prevent engagement of the actuator when in the dose preventing position to thereby prevent opening of the metering valve.

8. A system as in claim 7, wherein the lockout element has a distal end that is engageable with the canister to prevent substantial displacement of the canister into the housing when the lockout element is in the dose preventing position.

9. A system as in claim 8, wherein upon placement of the preventing device into the activated state, the distal end of the lockout element is retracted to permit displacement of the canister into the housing and to permit engagement of the actuator to open the metering valve.

10. A system as in claim 7, wherein the canister is movable within the housing when the preventing device is in the inactive state, and further comprising a stop that is reciprocally disposed within the housing below the actuator, and wherein the lockout element has a distal end that is engageable with the stop when in the activated state to prevent movement of the stop within the housing such that displacement of the canister engages the actuator with the stop to permit dispensing of the metered drug formulation when the preventing device is in the activated state.

11. A system as in claim 1, further comprising a high pressure gas source to assist in aerosolizing the drug formulation when the preventing device is in the activated state.

12. A system as in claim 1, further comprising a dose counter disposed to count the number of doses of the drug formulation dispensed from the container.

13. A system as in claim 12, wherein the container is reciprocatably disposed within a housing, and wherein the dose counter comprises a dose counting circuit positioned to sense when the container has been reciprocated within the housing.

14. A system as in claim 13, wherein the dose counter further comprises a display for indicating if the container contains an amount of drug formulation.

15. A system as in claim 5, further comprising a nozzle operably coupled to the canister, and wherein the housing further includes a mouthpiece disposed to receive the drug formulation from the nozzle.

16. A system as in claim 15, wherein the mouthpiece has a first end and a second end, and wherein the nozzle is positionable within an opening adjacent the first end of the mouthpiece to permit the aerosolized drug formulation to be delivered to a patient upon inhalation through the second end of the mouthpiece.

17. A method of aerosolizing a drug formulation, the method comprising:

providing a container having an amount of a drug formulation that is aerosolized in response to manual actuation;

preventing the manual actuation of the aerosolization of the drug formulation with an electronic lockout device by maintaining the lockout device is in an inactive state; and

supplying electrical current to the lockout device to place the lockout device in an active state, thereby permitting the manual actuation of the aerosolization of the drug formulation.

18. A method as in claim 17, wherein the electronic lockout device comprises a lockout element that is positioned in a dose preventing position when in the inactive state, and further comprising moving the lockout element to a dosing permitting position when electric current is supplied to place the lockout device in the activated state.

19. A method as in claim 18, wherein the container comprises a canister having a metering valve and an actuator, wherein the canister is reciprocatably held within a housing between a home position and a dosing position, and further comprising depressing the canister into the housing to the dosing position to engage the actuator and to release a metered amount of the drug formulation when the lockout device is in the active state.

20. A method as in claim 19, further comprising preventing engagement of the actuator when the lockout element is in the dose preventing position.

21. A method as in claim 20, further comprising engaging the canister with the lockout element to prevent movement of the canister to the dispensing position when the lockout element is in the dose preventing position.

22. A method as in claim 21, further comprising disengaging the lockout element from the canister to permit movement of the canister to the dispensing position upon supply of the electrical current.

23. A method as in claim 20, further comprising engaging the lockout element with a stop that is positioned below the actuator upon supply of the electrical current, and further comprising depressing the canister into the housing to engage the actuator with the stop.

24. A method as in claim 18, further comprising stopping the supply of the electric current to the lockout device after the drug formulation has been aerosolized .

25. A method as in claim 24, further comprising supplying electric current to the lockout device to permit another dosing only after a certain dosing condition has been satisfied.

26. A method as in claim 25, further comprising counting the number doses aerosolized from the container.

27. A method as in claim 26, further comprising displaying whether the container contains an amount of drug formulation based on the number of aerosolizations.

28. An aerosol drug delivery system comprising:

a housing having a mouthpiece;

a canister that is movable within the housing when manually depressed into the housing, the canister having a metering valve that is operable to release a metered amount of a drug formulation from the canister; and

a control system comprising a locking mechanism that may be in an activate or an inactivate state, wherein the control system controls the opening of the valve such that the valve is only opened when a force is manually applied to depress the canister into the

housing and when a dosing condition has been satisfied at which time the locking mechanism in the active state.

29. A system as in claim 28, wherein the control system comprises a controller, wherein the controller is configured to send a signal to the locking mechanism to activate the locking mechanism to permit opening of the valve once the dosing condition has been satisfied.

30. A system as in claim 29, wherein the dosing condition is the passage of a certain amount of time between dosings, and further comprising an electronic clock coupled to the controller to measure the passage of time between dosings.

31. A system as in claim 28, wherein the locking mechanism is normally in a dose preventing position and is movable to a dosing position when electrical current is supplied to the locking mechanism to permit opening of the valve when the canister is depressed.

32. A system as in claim 31, wherein the locking mechanism includes a locking element that engages the canister to prevent depression of the canister into the housing when in the dose preventing position.

33. A system as in claim 31, wherein the canister includes an actuator, and wherein the locking mechanism includes a locking element that engages a stop that in turn engages the actuator when in the dose permitting position and when the canister is depressed into the housing.

34. A method for administering a nicotine formulation for smoking cessation therapy, the method comprising:

providing an amount of a nicotine formulation;

preventing the aerosolization of the nicotine formulation with a lockout device when the lockout device is in an inactive state;

supplying electric current to the lockout device to place the lockout device in an active state; and

aerosolizing the nicotine formulation by manual actuation.

35. A method as in claim 34, further comprising controlling when electric current may be supplied to the lockout device based on a specified dosing schedule.

36. A system as in claim 1, wherein the container contains drug formulation which comprises nicotine.

(9) Evidence Appendix

none

(10) Related Proceedings Appendix

none